

**Remarks**

Claims 1-6, 8-31, and 60 are pending in this application. Claims 32-59 have been withdrawn. Claim 7 has been canceled. Claim 1 has been amended. New claims 60-63 have been added.

Support for the amendment to claim 1 can be found in the original specification at, for example, original claim 7, and page 4, lines 28-29.

Support for new claim 60 can be found in the original specification at, for example, original claim 1, and page 4, line 20.

Support for new claims 61-63 can be found in the original specification at, for example, page 4, line 20.

No new matter has been added.

**I. REJECTION OF CLAIMS 1-31 UNDER 35 U.S.C. § 103(a)**

Claims 1-5, 7-19 and 21-31 have been rejected as being allegedly obvious over International Publication No. WO 93/20859 (the "Arm PCT application"); claims 1, 2, 4, 5, 8-10 and 20 have been rejected as being allegedly obvious over U.S. Patent No. 4,610,692 to Eitenmuller *et al.* ("Eitenmuller"); and claims 1-6, 8-12 and 20 have been rejected as being allegedly obvious over U.S. Patent No. 5,670,161 to Healy *et al.* ("Healy") for the reasons set forth in the Office Action. Applicants respectfully traverse these rejections.

**A. Claims 1-5, 8-19 and 21-31 are not Obvious over the Arm PCT Application**

Amended claim 1 relates to an implant having a "varnish-like biodegradable polymer coating." Claim 1 further specifies that "the varnish-like biodegradable polymer forms an adhesive bond to the surface of the implant."

The Arm PCT application is directed to "a biodegradable film which can be affixed to an implantable or prosthetic device" (Arm PCT application, page 3, line 36 - page 4, line 1) (emphasis added). The Arm PCT application does not expressly describe what is meant by the term "affixed." Instead, the Arm PCT application teaches: "The biodegradable films of the present invention are particularly useful as coatings for prosthetic devices and surgical implants. The films may, for example, be wrapped around the outer surfaces of surgical screws, rods, pins, plates and the like" (Arm PCT application, page 13, lines 9-13) (emphasis added). The Arm PCT application exemplifies a method for producing a free-standing film by dissolving PLA and PLA/PGA polymer granules in chloroform and allowing the solvent to evaporate (Example 1 of Arm PCT application, page 15, lines 3-9).

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The Arm PCT application teaches that "[t]he films were then rolled around 0.9 mm diameter Kirschner wires (K-wires), resulting in an implant diameter of 2.8-3.0 mm" (Example 1 of Arm PCT application, page 15, lines 13-15) (emphasis added). Thus, the Arm PCT does not teach or suggest an implant coated with a varnish like polymer, let alone a polymer that forms an adhesive bond to the surface of the implant.

"When obviousness is based on a particular prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of the reference." *B.F. Goodrich Company v. Aircraft Braking Systems Corporation*, 72 F.3d 1577, 1582 (Fed. Cir. 1996).

The Arm PCT application does not teach or even suggest a "varnish-like" coating on an implant, but rather teaches implants that are wrapped by a preformed film. Thus, one of skill in the art would find no motivation to modify the wrapped implant of the Arm PCT application and make an implant with a "varnish-like" coating, let alone a coating having a "polymer that forms an adhesive bond to the surface of the implant" as recited in amended claim 1. *B.F. Goodrich Company*, 72 F.3d at 1582.

Therefore, in view of the above, Applicants respectfully submit that amended claim 1 and all claims depending therefrom are not obvious over the Arm PCT publication, and withdrawal of the rejection of claims 1-5, 8-19 and 21-31 (claim 7 having been canceled) under 35 U.S.C. § 103(a) is respectfully requested.

**B. Claims 1, 2, 4, 5, 8-10 and 20 are not Obvious over Eitenmuller**

As noted above, claim 1 relates to an implant having a "varnish-like biodegradable polymer coating." Amended claim 1 further specifies that "the biodegradable polymer has a mean molecular weight of 100 kDa or less."

Eitenmuller is directed to "discretely-shaped, porous bodies impregnated with a high concentration of therapeutically-active component, and a coating of biodegradable substance of varying thickness over at least a portion of one of these discretely-shaped, porous bodies, preferably over a number of these discretely-shaped porous bodies, to thus form the requisite implant system" (Eitenmuller, col. 4, lines 22-29). However, Applicants respectfully submit that Eitenmuller does not teach or even suggest a coating containing a biodegradable polymer, where the "biodegradable polymer has a mean molecular weight of 100 kDa or less" as recited in amended claim 1. *B.F. Goodrich Company*, 72 F.3d at 1582.

Therefore, in view of the above, Applicants respectfully submit that amended claim 1 and all claims depending therefrom are not obvious over Eitenmuller, and withdrawal of the rejection of claims 1, 2, 4, 5, 8-10 and 20 under 35 U.S.C. § 103(a) is respectfully requested.

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**B. Claims 1-6, 8-12 and 20 are not Obvious over Healy**

As noted above, claim 1 relates to an implant having a "varnish-like biodegradable polymer coating." Amended claim 1 further specifies that "the biodegradable polymer has a mean molecular weight of 100 kDa or less."

Healy is directed to an expandable, biodegradable stent. Healy states that the stent "preferably also incorporates surface coatings or thin films (about 25  $\mu$ m thick) designed to reduce the risk of thrombosis and to deliver bioactive agents." However, Applicants respectfully submit that Healy does not teach or even suggest a surface coating containing a biodegradable polymer, where the "biodegradable polymer has a mean molecular weight of 100 kDa or less" as recited in amended claim 1. *B.F. Goodrich Company*, 72 F.3d at 1582.

Therefore, in view of the above, Applicants respectfully submit that amended claim 1 and all claims depending therefrom are not obvious over Healy, and withdrawal of the rejection of claims 1-6, 8-12 and 20 under 35 U.S.C. § 103(a) is respectfully requested.

**II. NEW CLAIMS**

New independent claim 60 is directed to an implant "comprising a body having a varnish-like biodegradable polymer coating of a thickness of 100  $\mu$ m or less, wherein the implant comprises a base material which is not biodegradeable."

Neither the Arm PCT publication, Eitenmuller nor Healy discloses, teaches or suggests the recited implant. As discussed above, the Arm PCT publication does not disclose, teach or even suggest an implant having a varnish-like polymer, let alone an implant where "the varnish-like biodegradable polymer forms an adhesive bond to the surface of the implant" as recited in new independent claim 60. Eitenmuller is directed to a "sintered tricalcium phosphate implant" (*see, e.g., Eitenmuller, Abstract*). However, Eitenmuller does not disclose, teach or suggest an implant "compris[ing] a base material which is not biodegradeable" as recited in new claim 60. Healy is directed to a "biodegradable stent" (*see, e.g., Healy, Abstract*). However, Healy does not disclose, teach or suggest an implant "compris[ing] a base material which is not biodegradeable" as recited in new claim 60.

New dependent claims 61-63 depend directly or indirectly upon new independent claim 60, so these claims are allowable for the reasons discussed above.

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### III. CONCLUSIONS

In view of the foregoing amendments and remarks, it is submitted that all rejections have been overcome and should be withdrawn, and all claims are in condition for allowance. Reconsideration of the application in view of the foregoing amendments and remarks is respectfully requested. The Examiner is invited to call the undersigned if a telephone call could help resolve any remaining items.

Respectfully submitted,

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